APPENDIX A

No. 07-5509

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

Filed Dec 7, 2007

Mal Son Halliman, Robert W. Halliman	)	
Plaintiffs-Appellants	)	On appeal from the United States District Court for the Middle District of Tennessee
v.	)	
UNITED STATES Of AMERICA	)	
Defendant-Appellee	)	
United States Army; Blanchfield Army Community Hospital; Darwin D. Karr-Peterson, LTC. Ret.	)	
Defendants	)	

ORDER

Before: BOGGS, Chief Judge; GIBBONS, Circuit Judge; BELL, Chief District Judge.

Mal Son Halliman and Robert W. Halliman, wife and husband, appeal pro se the summary judgment for the United States in a case filed under the Federal Tort Claims Act (FTCA), 28 U.S.C. § 1346(b)(1). This case has been referred to a panel of the court pursuant to Rule 34(j)(1), Rules of the Sixth Circuit. Upon examination, this panel unanimously agrees that oral argument is not needed. Fed.R.App.P. 34(a).

The Hallimans filed a complaint against an army surgeon, a hospital, the Army, and the United States, alleging that the surgeon committed malpractice when Mal Son Halliman's colon was punctured during a colonoscopy and that her follow-up care was also deficient. Mal Son Halliman pointed out that she is not a native English-speaker and that she believed the colonoscopy was going to be performed by a different doctor. Her administrative claim had been denied due to her failure to produce a medical expert to support her claim.

The defendant United States moved for summary judgment on the sole ground that the Hallimans had not submitted any expert testimony to support their claim. A magistrate judge recommended that the motion be granted. Over the Hallimans" objections, the district court adopted the magistrate judge's recommendations and granted summary judgment to the United States; the remaining defendants were dismissed in a separate final judgment order.

On appeal, the Hallimans challenge only the summary judgment for the United States, reasserting the arguments they raised below.

Upon de novo review, we conclude that the summary judgment for the United States must be affirmed because there is no genuine issue of material fact and defendant is entitled to judgment as a matter of law. *LaPointe v. United Autoworkers Local 600,* § F.3d 376, 378 (6th Cir. 1993).

Under Tennessee law, expert witnesses are required to support acclaim of malpractice. Tenn.Code Ann. § 29-26-115. Defendant pointed out in its motion for summary judgment that the Hallimans had produced no expert witnesses and therefore could not establish an essential element of their case on which they bore the burden of proof. *Celotex Corp. v. Catrett,* 477 U.S. 317, 322-23 (1986). The Hallimans argue that defendants are required to do more than point to an absence of evidence to support a plaintiff's case to successfully move for summary judgment under Tennessee Law. However, federal rules of procedure apply in federal district courts. *Gafford v. General Elec. Co.,* 997 F.2d 150, 165-66 (6th Cir. 1993).

The Hallimans also argue that there are exceptions to the requirement of supporting a malpractice complaint with expert testimony. They cite *Seavers v. Methodist Med. Ctr. Of Oak Ridge,* 9 S.W. 3d 86 (Tenn. 1999), for the proposition that expert testimony may not be necessary to prove negligence. The court in *Seavers* did hold that the doctrine of res ipsa loquitur could raise an inference of negligence

but also noted that expert testimony was necessary to prove other elements of a malpractice case, such as the standard of care. *Id.* at 96. The Hallimans also argue that expert testimony is not necessary in claims of informed consent or medical battery, citing *Blanchard v. Kellum,* 975 S.W. 3d 522 (Tenn. 1998). *Blanchard,* however, expressly states that expert testimony is required for informed consent claims *Id at 524.* Although it provides that expert testimony is not necessary for medical battery claims,, it also defines such claims as involving patients who did not know of or authorize a medical procedure. *Id.* In this case, the evidence showed that Mal Son Halliman knew she would be undergoing a colonsoscopy and had authorized its performance. The Hallimans attempt to add a requirement that she had to know which doctor would be performing the procedure, but a reading of *Blanchard* does not support the existence of such a requirement.

Accordingly, the summary judgment for the United States is affirmed for the reason stated by the magistrate judge and adopted by the district court. Rule 34(j)(2)©, Rules of the Sixth Circuit.

ENTERED BY ORDER OF THE COURT

Leonard Green, Clerk

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

FILED 2-27-2007

Mal Son Halliman, et.al.	)	
	)	No. 3:06-0037
v.	)	JUDGE CAMPBELL
	)	
UNITED STATES	)	
OF AMERICA, et.al.	)	
	)	

ORDER

Pending before the court are a Report and Recommendation of the Magistrate Judge (docket No. 26) and the Plaintiff's objections thereto (Docket Nos. 29 and 30). The court has reviewed the Report and Recommendations, Plaintiffs' Objections, and the file. Plaintiffs' Objections are overruled and the Report and Recommendation is adopted and approved.

Accordingly, the Motion for Summary Judgment filed by Defendant United States (Docket No. 20) is GRANTED, and Plaintiffs' claims against the United States are DISMISSED.

Three named Defendants remain in this actions (United Stated Army, Blanchfield Army Community Hospital, and Darwin D. Karr-Peterson). Al-

though Defendant United States has denied that these three are appropriate Defendants (Docket No. 15 ¶ 3), No Order has been sought or entered dismissing them.

Accordingly, this matter remains set for trial on May 29, 2007, with a pretrial conference on May 14, 2007.

IT IS SO ORDERED

TODD J. CAMPBELL
UNITED STATES DISTRICT JUDGE

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APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

FILED 2-15-2007

Mal Son Halliman, et.al.	)	
Plaintiffs	)	No. 3:06-0037
v.	)	Judge Campbell/Bryant
	)	
UNITED STATES OF	)	
AMERICA, et.al.	)	
Defendants	)	

To: The Honorable Todd J Campbell

REPORT AND RECOMMENDATION

The District Judge referred this case to the Magistrate Judge pursuant to 28 U.S.C. § 636 and 72, Federal Rules of Civil Procedure, for a report and recommendation on ay dispositive motions (Docket entry No. 3). Magistrate Judge Brown thereafter transferred this case to the undersigned (Docket Entry No. 19).

Pending before the court is defendant's motion for summary judgment, premised upon the plaintiffs' lack of an expert witness (Docket Entry No. 20).

For the reasons stated below, the undersigned RECOMMENDS that defendant's motion for summary judgment be GRANTED and that the complaint be DISMISSED.

The Complaint

Plaintiffs Mal Son Halliman and husband, Robert W. Halliman, proceeding pro se, have filed this medical malpractice action pursuant to the Federal Tort Claims Act, 28 U.S.C. § 1346 (b)(1), seeking to recover damages allegedly sustained by plaintiffs as the result of a negligently performed colonoscopy on Mrs. Halliman at Blanchfield Army Community Hospital on September 10, 1999. The complaint alleges (1) that the Army surgeon who performed the colonoscopy breached the standard of care by using excessive force that caused a perforation; (2) that the surgeon was negligent in his follow-up care of Mrs. Halliman; (3) that that the surgeon failed to obtain Mrs. Halliman's informed consent by failing to inform her adequately of the risks of the procedure, in view of her inability to read and write English, before securing her signature on the surgical consent form; and (4) that the staff of Blanchfield Army Hospital breached the standard of care by their poor postoperative care of Mrs. Halliman.

Defendant's Summary Judgment Motion

By order of the court, plaintiffs were to serve their Rule 26(a)(2)(B) expert witness reports on or

before August 31, 2006 (Docket Entry No. 17). This deadline has expired and plaintiffs have served no expert witness reports. Defendant has filed its motion for summary judgment pursuant to Rule 56, Federal Rules of Civil Procedure, premised on the sole ground that "plaintiff has not obtained or retained an expert medical witness to support the allegations in her complaint and who has agreed to testify in this case." (Docket Entry No. 22). Defendant argues that, without an expert witness, plaintiffs as a matter of law are unable to establish a genuine issue of material fact for trial. Plaintiffs, in response, maintain (1) that merely asserting plaintiffs' lack of proof is insufficient to support a motion for summary judgment, and (2) that the complaint includes a claim of medical battery, which does not require expert testimony (Docket Entry No. 24).

Analysis

In actions brought under the Federal Tort Claims Act, the Court is required to apply the law of the place where the alleged negligent act or omission of the government occurred. Richards v. United States, 3 U.S. 1, 9-10 (1962); Lloyd v. Cessna Aircraft Co., 434 F. Supp. 4, 5 (E.D. Tenn. 1976). Accordingly, the law of Tennessee applies to this medical malpractice claim against the government.

Tennessee Code Annotated section 29-26-115(a) lists the elements of a medical malpractice claim under Tennessee law, as follows:

> In a malpractice action, the claimant shall have the burden of proving by evidence as provided by subsection (b); (1) The recognized standard of acceptable professional practice in the profession and the specialty thereof, if any, that the defendant practices in the community in which or in a similar community at the time the alleged injury or wrongful action occurred.
>
> (2) that the defendant acted with less than or failed to act with ordinary and reasonable care in accordance with such standard; and
>
> (3) As a proximate result of the defendant's negligent act or omission, the plaintiff suffered injuries which would not otherwise have occurred.

Subsection (b) of this provision states that no person shall be competent to testify as an expert to establish the elements in subsection (a) unless the person was licensed and practicing in Tennessee or a contiguous bordering state during the year before the alleged injury or wrongful act occurred. Tenn.Code Ann. § 29-26-115 (b).

In Tennessee, negligence and causation in medical malpractice cases are ordinarily required to be proved by expert medical testimony. Stokes v. Leung, 651 S.W. 2d 704, 706 (Tenn. Ct.App. 1982).

Rule 56 (c) of the Federal Rules of Civil Procedure, describing summary judgment, states in pertinent part as follows:

> The judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admission on file, together with affidavits, if any, show that thee is no genuine issue of any material fact and that the moving party is entitled to judgment as a matter of law.

(emphasis added). Here, the defendant seeks to establish that there is "no genuine issue of any material fact" for trial by asserting (1) that plaintiffs have not obtained a medical expert witness to testify at trial, and (2) that under Tennessee law expert testimony is required to prove the elements of a medical malpractice case. Plaintiffs, in response, apparently concede that they have no medical expert, but they argue (1) that under Tennessee law merely asserting the plaintiffs' lack of proof is insufficient to support a motion for summary judgment, and (2) that their complaint includes a claim for medical battery that does not require expert witness testimony.

The first issue present here is whether a defendant must negate an essential element of the plaintiffs' case in order to sustain a motion for summary judgment, or whether, instead, merely asserting the plaintiffs' lack of evidence is sufficient. On this issue Tennessee and federal law differ. Tennes-

see courts have held that merely asserting a plaintiff's lack of evidence is insufficient to support a motion for summary judgment. See McCarley v. West Quality Food Services, Inc., 960 S.W. 2d 585, 589 (Tenn. 1998); Byrd v. Hall, 847 S.W. 2d 208, 214 (Tenn. 1993). Speaking to this issue, the Tennessee Supreme Court has stated:

> A party seeking summary judgment must demonstrate the absence of any genuine and material factual issues. Byrd v. Hall, 847 S.W. 2d 208, 214 (Tenn. 1993). Mere "conclusory assertion (s) that the non-moving party has no evidence is clearly insufficient." Id. At 215. The movant must either affirmatively negate an essential element of the non-movant's claim or conclusively establish an affirmative defense. Id.at 215 n. 5. If the movant does not negate a claimed basis for the suit, the non-movant's burden to produce either supporting affidavits or discovery materials is not triggered and the motion for summary judgment fails. Id.

McCarley, 960 S.W. 2d at 588. Thus, under Tennessee law, the government's assertion that plaintiffs are without expert witness testimony would be insufficient to support a motion for summary judgment.

In contrast, the U.S. Supreme Court has held that it is not necessary to negate an essential element of the plaintiff's case. The Court stated as follows:

> In our view, the plain language of rule 56 (c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. In such a situation, there can be "no genuine issue as to any material fact," since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial.
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> . . .
>
> But unlike the Court of Appeals, we find not express or implied requirement in Rule 56 that the moving party support its motion with affidavits or other similar materials negating the opponent's claim. On the contrary, Rule 56 (c), which refers to "the affidavits, if any" (emphasis added), suggest the absence of such a requirement.

Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986) (emphasis in original). Accordingly, if federal law governs, the government is not required to negate an element of plaintiffs' case, and a suggestion of plaintiffs' lack of expert testimony is sufficient.

Although the substantive medical malpractice law of Tennessee governs this case, Richards v. United States, 369 U.S. at 9-10, Rule 56 of the Federal Rules of Civil Procedure has been held to control summary judgment practice in district court, unaffected by state procedural rules. Schultz v. Newsweek, Inc. 668 F. 2d 911, 917 (6th Cir. 1982). The Court of Appeals for the Sixth Circuit has stated:

> Gafford next contends that the district court erred in applying Rule 56 of the Federal Rules of Civil Procedure instead of the Kentucky summary judgment standard in disposing of GE's motion for summary judgment. She essentially argues that, since Kentucky's procedural rules and case law relating to summary judgment affect substantive legal rights, a federal court in diversity should apply Kentucky's summary judgment standard as expressed in Steelvest, Inc. v. Scansteel Serv. Ctr., Inc. 807 S.W. 2d 476 (Ky. 1991). Gafford's argument is readily put to rest. This court rejected such an argument in Reid v. Sears, Roebuck & Co., 790 F. 2d. 453, 459 (6th Cir. 1986). In

that case, employees asserted claims of wrongful discharge in a Michigan state court. The claims were removed to federal court on the basis of diversity of citizenship. The district court granted summary judgment in favor of the employer, and the employees appealed. The employees argued, inter alia, that the court erred in applying the standards of Rule 56 of the Federal Rules of Civil Procedure to the case. This court expressly rejected that argument;

> "(One of the employees contends that) Sears would not have qualified for summary judgment under Michigan law and that the outcome of a diversity case should not be different in a federal court than it would have been in the state whose substantive law controls. This argument fails to recognize the difference between procedural rules and substantive laws. The Federal Rules of Civil Procedure are the rules of practice which apply to civil actions in the federal courts, regardless of whether jurisdiction is based federal question or diversity of citizenship."

Gafford v. General Electric Co., 997 F.2d 150, 165-66 (6th Cir. 193) (quoting Reid v. Sears, Roebuck & Co., 790 F.2d 453, 459 (6th Cir. 1986). Thus, federal procedural law controls the disposition of the government's motion for summary judgment and, to the

extent that plaintiffs' case depends upon expert witness testimony, the plaintiffs' failure to produce expert testimony supporting their case requires that the government's motion be granted.

The second issue raised by plaintiffs' response is whether plaintiffs' claim constitutes a medical battery that can proceed without expert testimony. Plaintiffs argue that it does, and they cite the case of Blanchard v. Kellum, 975 S.W.2d 522 (Tenn. 1998). In a typical medical case alleging lack of informed consent, Tennessee statutory law requires expert testimony to prove that the information provided by a practitioner to the patient did not comply with the standard of care in the community. See Tenn. Code Ann. § 29-26-115. However, the Tennessee Supreme Court has distinguished a medical battery from a typical informed consent case. The Blanchard court stated as follows:

> We believe that there is a distinction between: (1) cases in which a doctor performed an unauthorized procedure; and (2) cases in which the procedure is authorized but the patient claims that the doctor failed to inform the patient of any or all the risks inherent in the procedure. Performance of an unauthorized procedure constitutes a medical battery. A simple inquiry can be used to determine whether a case constitutes a medical battery: (1) was the patient aware that the doctor was going to perform the procedure (i.e., did

> the patient know that the dentist was going to perform a root canal on a specified tooth or that the doctor was going to perform surgery on the specified knee?); and, if so (2) did the patient authorize the performance of the procedure? A plaintiff's cause of action may be classified as a medical battery only when answers to either of the above questions are in the negative. If, however, the answers to the above questions are affirmative and if the plaintiff is alleging that the doctor failed to inform of any of the risks or aspects associated with a procedure, the patient's cause of action rests on an informed consent theory.

975 S.W.2d at 524.

From a review of the complaint, it appears that plaintiffs concede that Mrs. Halliman knew that she was to have a colonoscopy on December 10, 1999, and that she consented to it. In the "Background" paragraph of her complaint, Mrs. Halliman states in part: "although my (sic) I really did not want the procedure, my husband convinced me to agree to the colonoscopy." Elsewhere in the complaint Mrs. Halliman states as follows:

> It must be kept in mind that I am Korean and do not read English. While I understand basic spoken English, I have difficulty comprehending expla-

> nations that are complex. The consent form was signed on December 6, 1999. My husband was not present at that time because he was working in Louisiana. It is highly that I signed the consent form without fully comprehending what the risks were. Because I am obsessive compulsive and would have had a tremendous fear of the procedure had I known the risk, I would not have consented to the procedure had I fully comprehended what the risk was.

From this allegation it is clear that plaintiffs' claim is not a medical batter as defined by Blanchard, but instead is an informed consent claim that requires expert testimony pursuant to Tennessee Code Annotated § 29-26-118.

In summary, plaintiffs' claims of medical malpractice and of lack of informed consent both must be proved by expert testimony under Tennessee law. In the absence of expert testimony to support plaintiffs' claims, there can be "no genuine issue as to any material fact," since a complete failure of proof concerning an essential element of the plaintiffs' case renders all other facts immaterial. Celotex, 477 U.S. at 323. Summary judgment for defendant is therefore appropriate.

RECOMMENDATION

For the reasons stated above, the undersigned RECOMMENDS that the government's mo-

tion for summary judgment be GRANTED and the complaint DISMISSED.

Under Rule 72(b) of the Federal Rules of Civil Procedure, any party has ten (10) days from receipt of this Report and Recommendation in which to file any written objections to this Recommendation, with the District Court. Any party opposing said objections shall have ten (10) days from receipt of any objections filed in this Report in which to file any response to said objections. Failure to file specific objections within ten (10) days of receipt of this Report and Recommendation can constitute a waiver of further appeal of this Recommendation. Thomas v. Arn, 474 U.S. 140 (1985), reh'g denied. 474 U.S. 1111 (1986).

ENTERED this 15th day of February, 2007.

s/ John S. Bryant
JOHN S. BRYANT
United States Magistrate Judge

APPENDIX D

Tennessee Code Annotated

§ 29-26-115. Claimant's burden in malpractice action – Expert testimony – Presumption of negligence – Jury instructions

(a) In a malpractice action, the claimant shall have the burden of proving by evidence as provided by subsection (b):

1. The recognized standard of acceptable professional practice in the profession and the specialty thereof, if any, that the defendant practices in the community in which the defendant practices or in a similar community at the time the alleged injury or wrongful action occurred;

2. That the defendant acted with less than or failed to act with ordinary and reasonable care in accordance with such standard; and

3. As a proximate result of the defendant's negligent act or omission, the plaintiff suffered injuries which would not otherwise have occurred.

(b) No person in a health care profession requiring licensure under the laws of this state shall be competent to testify in any court of law to establish the facts required to be established by

subsection (a),unless the person was licensed to practice in the state or a contiguous bordering state a profession or specialty which would make the person's expert testimony relevant to the issues in the case and had practiced this profession or specialty in (1) of these states during the year preceding the date that the alleged injury or wrongful act occurred. This rule shall apply to expert witnesses testifying for the defendant as rebuttal witnesses. The court may waive this subsection (b) when it determines that the appropriate witnesses otherwise would not be available.

(c) In a malpractice action as described in subsection (a), there shall be no presumption of negligence on the part of the defendant; provided, there shall be a rebuttable presumption that the defendant was negligent where it is shown by the proof that the instrumentality causing injury was in the defendant's (or defendants') exclusive control and that the accident or injury was one which ordinarily doesn't occur in the absence of negligence.

(d) In a malpractice action as described in subsection (a), the jury shall be instructed that the claimant has the burden of proving, by a preponderance of the evidence, the negligence of the defendant. The jury shall be further instructed that injury alone does not raise a presumption of the defendant's negligence.

§ 29-26-118 Proving inadequacy of consent. –

In a malpractice action, the plaintiff shall prove by evidence as required by § 29-26-115(b) that the defendant did not supply appropriate information to the patient in obtaining informed consent (to the procedure out of which plaintiff's claim allegedly arose) in accordance with the recognized standard of acceptable professional practice in the profession and in the specialty, if any, that the defendant practices in the community in which the defendant practices and in similar communities

APPENDIX E

Informed Consent in Clinical Medicine*

Peter B. Terry, MD, MA, FCCP

Over the past third of a century, there has been a revolution in the way that health-care providers and patients make most medical decisions. Paternalism has slowly gone the way of the long-play record, and in its place has emerged a consent process in which the patient is a more fully

informed and active participant. This process takes time however, and for the busy health-care provider there is often the temptation to hand the patient a consent form to sign. It is important to realize that signing a consent form does not constitute informed consent. True informed

consent is a process, and, as such, it requires that the health-care provider enter into a discussion that ultimately leads to the patient understanding of their options, and the risks and benefits of the alternative courses of action. The purpose of this article was to describe, in some detail, the consent process in practical clinical terms, and to note when and how it should be obtained.

Just as medicine has evolved over the past 200 years into a sophisticated profession that can often alleviate symptoms and cure disease, so also has the physician-patient relationship evolved from one of paternalism to one of a more equal partnership in the United States.1 A cornerstone of this new relationship is the belief that respect for patients and

their values is right and essential to good medical care. From this flows the obligation to obtain a patient's informed consent when decisions must be made about significant diagnostic and therapeutic interventions. But what is informed consent? The concept of informed consent has been evolving over the past 100 years based largely on case law early in the last century and later influenced by the Nuremberg trials, influential articles such as those of Henry Beecher, and contemporary bioethical thought beginning in the 1960s in the United States.2–5 Informed consent in medical research will be discussed in a subsequent article in this series.

Informed consent may be defined as the autonomous act by a patient or research subject to expressly permit a professional person to perform a medical action on the patient or to include a person in a research project.2 Although much has been written about each element of this definition (eg, autonomous act, expressly permitted), and its philosophical underpinnings, it seems most important for the busy physician to understand the practical implications of this definition. Below are cases that exemplify important aspects of informed consent.

Elements of Informed Consent

Case 1

A pulmonologist, seeing a patient in the outpatient clinic for a new asymptomatic infiltrate, recommends bronchoscopy. She hands the patient a detailed consent form that describes the risks, benefits, and alternatives to bronchoscopy, and asks

him to take his time reading it. Coming back a few minutes later, the pulmonologist asks the patient if he has any questions. The patient has none and signs the consent form, which is witnessed by a nurse.

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Has the physician obtained informed consent? Yes and no.

Yes, from the legal and administrative perspective of a hospital the physician has obtained consent. Indeed, some hospitals have a patient sign a generic "consent-to-treat" form on admission. However, a signed consent form does not prevent a lawyer from pursuing a malpractice suit nor does it ensure a legal judgment in favor of the physician.

No, from the perspective of obtaining an ethically valid form of consent, the patient has not given consent. Informed consent is not a signed piece of paper; it is a process.2 What is written on a consent form is only a part of the process. A consent form gives information, but it does not give understanding, an obligation that a physician obtaining consent needs to ensure.

Obtaining true informed consent consists of a number of critical elements.2 These include the following: (1) disclosure of the pertinent medical facts and alternative courses of action; (2) ensuring patient capacity to understand the decision to be made; (3) ensuring patient understanding of the medical information; (4) the absence of coercion or manipulation; and (5) the

ability to consent. There are no national standards enumerating which procedures or decisions require informed consent by the patient in the United States.6 Indeed,

in one study6 marked variability within and between hospitals was found in obtaining informed consent for procedures among ICUs and internal medicine programs. At present, hospitals and their medical

staffs are left to develop local guidelines for obtaining consent. Although there is no formally recognized threshold of risk above which we ought to obtain informed consent, one ethical guideline might be any risk that is of a greater magnitude than that which we might ordinarily encounter when carrying out normal daily activities. Future guidelines for when to obtain informed consent in gray areas may be developed by determining societal expectations. Some hospitals have attempted to amalgamate the consent process into a single blanket consent signed early in the hospital course.6 This may be administratively acceptable but is not ethically acceptable unless the patient waives their right to make decisions.

Disclosure: When are physicians obligated to disclose information about a treatment or test? When a physician performs a venipuncture to obtain a blood sample from an adult patient, the physician does not feel obligated to obtain written or verbal consent. Because the risks are small, and because most adults have already had a venipuncture, they know what to expect. However, when a thoracic

surgeon sits down with a patient about to undergo lung transplantation, the surgeon feels obligated to carefully discuss all of the risks, benefits, and alternatives to having surgery. These two scenarios represent ends of the spectrum of the concept of proportionality with respect to disclosure. The notion of proportionality suggests that the greater the risk we are asking the patient to expose themselves to, the greater our obligation to disclose the risks, benefits, and alternatives to the procedure.

What has to be disclosed to the patient? Clearly, the physician must disclose enough information so that the patient can make an informed decision. What that entails has been evolving over the last 100 years.2 At the beginning of the 20th century, the standard (whatever the physician felt should be disclosed). With the influence of case law and contemporary bioethics, the standard has become one in which the physician must disclose the information that a reasonable person would want to know before making a decision. This so-called prudent-person standard applies to information about the harms, benefits, and alternative treatment strategies. The concepts of likelihood and magnitude of harm also assist the physician in deciding what risks to disclose when talking about diagnostic and therapeutic decisions. A reasonable guideline is to describe the complications/side effects that have a high likelihood of occurring even if they are minor in nature (eg, nausea or transient fever), and to describe the complications/side effects that have a low but not rare likelihood of occurring but are of such a magnitude of harm that they would give the pru-

dent person pause when making decisions (eg, 5 to 10% chance of dying). Complications and side effects that have a moderate chance of occurring and are mild or moderate in their severity should be disclosed, dependent on the circumstances. When obtaining consent and after giving the patient information that a reasonable person would want to know, it is vital to ask the patient whether there is any other information needed to make a decision. This allows the patient to ask questions, and thus sets an even higher standard, a subjective standard of disclosure. By asking whether there is anything else the patient wishes to know, this allows the patient to ask questions that reflect their unique sense of values and concerns. For example, some patients are more risk averse than others, and want to know more about the likelihood and consequences of complications or side effects than the physician would discuss with the average patient.

Capacity and Competence: Capacity is a medical concept and Implies that a patient has the ability to understand and weigh medical information and make decisions. Capacity may fluctuate (eg, whenthe patient goes in and out of a delirium). Most patients have the ability to understand simple choices, but **as the risks and benefits of choices increase in magnitude and complexity some with limited capacity or less formal education may be unable to give true informed consent.** Again

the concept of proportionality applies here. As the complexity of a decision and the magnitude of the consequences increase, so does the physician's obligation to ensure that the patient has the capacity to make the decision. Asking the patient to describe the treatment or test and its risks, benefits, and alternatives will often allow the physician to determine whether the patient has the capacity to understand and weigh the choices at hand. If there is a concern, asking the patient questions that test mental status is appropriate.7 More formal cognitive testing and a psychiatric consultation may be appropriate in some instances. **Even when the patient has the capacity to make a decision, the patient may not understand the words or concepts presented by the physician**. For example, a 10% chance of a complication may need to be translated into "for every 100 people who have this procedure, 90 of them will not have the complication, but 10 will." It is important to understand that capacity and competence mean different things. Competence is a legal term. Society and the law presume all persons to be competent until legally judged otherwise. A judicial declaration of incompetence is a legal declaration that the patient can no longer manage his or her affairs. This declaration may only be made or rescinded by a judge. Guardianship generally follows when a person is declared to be legally incompetent. Physicians and families routinely make decisions for patients who have been judged to be incapacitated without subjecting the patient to a formal competence hearing. This is justifiable if the patient has been judged by the physician to be

incapable of understanding the nature of the decision, its alternatives, and the accompanying risks, benefits, and consequences.

A less commonly recognized problem related to capacity is that of acceptance. A patient may understand all of the factual information that the physician gives him or her, but may not believe that some of it is true. For example, a patient in the ICU may have a life-threatening illness, be told about it, and be able to comprehend the risks and the benefits of the treatment options, but makes a decision that he or she would not otherwise make because the patient does not accept the life-threatening nature of the illness. When it is determined that a patient does not have the capacity to make the medical decision at hand, a surrogate (ie, a substitute decision maker) should make the decision. Ideally, all persons would have named a surrogate via an advance directive. In fact, most patients have not, so that we traditionally turn to the immediate family to act in the patient's best interest. Studies have shown that the person the patient would want to make decisions for him/her (ie, the moral surrogate) is usually the same person that state law would name as the decision maker (legal surrogate).8 Occasionally, the legal surrogate does not act in the patient's best interest (ie, is not also the moral surrogate). In such instances, the physician must ensure, if necessary through an ethics committee and/or court proceedings, that someone who will act in the patient's best interest is named.

Physicians may be asked to offer guidance to the surrogate in terms of how decisions should be made. The first suggestion is that the surrogate try to make a decision based on prior discussions with the patient (known as substituted judgment). In the absence of such discussions, the physician should suggest that the surrogate make the decision based on his or her best sense of the values and beliefs of the patient (knows as best interest judgment). If the surrogate has had little contact with the patient and does not know the values and beliefs of the patient, then the surrogate should be advised to make a decision that a prudent person would make in the circumstances. In the absence of detailed discussions with patients about their preferences for various treatments, there is a reasonable likelihood that the family (ie, surrogates) cannot accurately predict what decision the patient would make.8–10 Is this a persuasive argument against family members (surrogates) making decisions for patients? Most who have thought about this argue that this is not a compelling reason to dismiss family decision making as being invalid. In one study,11 when patients were asked whose preferences should prevail when there was a conflict between the patient's advance directive and the family's wishes, more than half the patients said that their advance directive should be ignored and the family's wishes followed.

Physician Decision-Making Influence: There are three ways that a physician can influence a

patient's decision making. These are rational persuasion, coercion, and manipulation.5 Rational persuasion implies that the patient makes the decision based on the logic of the factual information the physician has given coupled with the patient's own values. Ideally, physicians should use only this method of influencing patient decision making. Coercion implies that the patient is threatened in some way, such that a decision is made that the patient may not

Case 2

A physician believes that the best decision that a patient can make related to an impending elective surgical procedure is to refuse it. The physician also knows that the patient is very risk averse. So the physician, during the process of obtaining informed consent, tells the patient (while raising her eyebrows) that he has a 5% chance of dying as a result of a complication of the surgery. The physician could have given the patient the same information by saying that the patient had a 95% chance a having a successful surgery but chose to emphasize the risks in order to influence the patient to make the decision the way that the physician wanted it to be made. This more pervasive and subtle but inappropriate form of presenting information is called manipulation. Manipulation implies that the physician gives information to the patient either selectively or through emphasizing or deemphasizing some information inappropriately so as to make attractive to the patient the decision that the physician thinks is best for the

patient. A common form of manipulation is called framing. Consciously or unconsciously, physicians will often frame information, emphasizing or minimizing the risks or benefits of one of the choices so that the patient makes the decision that the physician wants them to make. The patient does not know that as we are presenting the choices to them in a seemingly objective manner, we are actually conflating the factual information of decision making with our own opinion about what is the best decision. It is better to state the facts objectively and then separately give the patient your opinion about the best course of action.

Ability to Consent: Rare instances may occur in which a patient fulfills all of the other criteria for informed consent but cannot give consent. For example, a patient may be in a "locked-in" state and may literally be unable to convey the decision to the health-care providers, even though they may have made an informed decision.

Who Should Give Informed Consent

Case 3

The condition of an 81-year-old retired janitor, who was not previously your patient but is now under your care, is deteriorating in the ICU. A decision must be made about resuscitation. The patient is alert, cooperative, and, in your judgment, appears to have the capacity to make any necessary decisions. You discuss the treatment options, risks, and benefits with the patient, and, after much dis-

cussion, you ask him what he would prefer that you do. Is this the right question to ask? No, because this question presumes that he wants to make the decision. Additionally, the patient may have assumed that he must make the decision because you asked. It is widely recognized that patients have the right to make decisions for themselves. But many mistakenly believe that because this right exists, patients must and will always choose to exercise it. There is a growing body of empirical evidence suggesting that in a variety of circumstances patients would prefer not to make decisions by themselves. Rather, they often want to share decision making with family and/or their physician or want others to make decisions on their behalf. These observations suggest that, when obtaining informed consent, we ask first who and how they want to make decisions, rather than what decision they want to make.

Cultural Diversity and Informed Consent

Sensitivity to cultural values must always be an important consideration when obtaining informed consent, and the United States, which is a country of immigrants, is increasingly a multicultural society. Importantly, many cultures place family values above those of the individual and do not value the individual decision making that has become common practice in the past half century. For example, it is considered an insult in some Arabic cultures if the physician asks the patient to sign a consent document.

It is essential to understand the culture of a pa-

tient and, if necessary, meet the patient privately, perhaps with the help of an interpreter, to determine what information the patient wishes to know and how the patient wishes the consent process to proceed. Do not use family as interpreters because they may not accurately express the patient's wishes. If patients choose to allow their spouses, family, or elders to make decisions on their behalf, then they have expressed their autonomous wish to allow others to make these decisions.

When Consent Is Unnecessary

Case 4

A young woman in your ICU is in shock secondary to massive pulmonary emboli. Because of the small, isolated nature of the hospital, there are no surgical or transport options available. You have the capacity to give the patient a thrombolytic agent but wish to

obtain informed consent from her next-of-kin because of the significant risks associated with its use. After many frantic attempts to contact a family member, none is found. Should you give her the

agent without obtaining consent? It is not necessary to obtain informed consent in emergency circumstances if delay will increase the risk of significant harm and there is a reasonable likelihood that the patient will benefit from the treatment. The challenge is in defining what we mean by the terms significant harm and benefit. The meaning of harm and benefit must be determined by the physician in the clinical context. In the case cited in previous sections, most would agree that death is a likely

significant harm without treatment. Most physicians would agree that there is significant chance of benefit from the use of the thrombolytic agent. But there may be disagreement as to whether the likelihood of an intracranial bleed secondary to therapy constitutes a significant risk.

Another circumstance in which it is not necessary to obtain informed consent occurs when a patient waives the right to go through the informed consent process. Some patients trust their physician or family implicitly, do not wish to know certain information related to decision making, and may waive their right to give consent. This is ethically and legally acceptable, but may be psychologically burdensome to the family/physician and has the potential to expose the patient to abuse.[5,17] Alternatively, some patients wish to know and understand the choices before them, but choose to let the physician make decisions on their behalf.

A rarely invoked reason not to obtain informed consent is what is known as the therapeutic privilege. Some states legally allow a physician to withhold information needed by the patient to give informed consent if there is a reasonable likelihood that the patient would be harmed by hearing the information. An example might be the withholding of information from a severely depressed patient who has attempted suicide in the past when given similar information. This does not mean that the patient should never be given important information in such circumstance; rather, if they are told, the

in such circumstance; rather, if they are told, the physician must make preparations in advance to reduce the patient's risk of self-harm by involving psychiatry and the patient's family in the disclosure process.

Assent

A 16-year-old person may have the capacity to give ethical consent (called assent) but cannot sign the hospital consent form because of age restrictions on the definition of an adult. At progressively younger ages, the ability of a child to reason becomes questionable,

but it remains incumbent on the physician to help minors understand, as much as possible, the decision that must made by their parents and to obtain their assent to the decision.

Conclusion

Informed consent is a cornerstone of patient-physician interactions. Even the most mundane of patient-physician interactions, that of writing a prescription, is an opportunity to practice I formed

consent and may even enhance patient adherence. It can be time consuming and frustrating, especially when the patient makes a choice with which the physician does not agree. But as physicians we must be cautious not to inject our own sense of values into decision making unless it is clear to the

patient what part of the discussion is factual and what part reflects our values and opinion. We must continually remind ourselves that it is our responsibility to give the patient the information they need to make a decision and to ensure that they understand it. Informed consent exists to allow the patient to pursue their life plan by safeguarding their values and facilitating a rational decision-making process.